

22
b) detecting an immunological reaction between the bacterial strain or the bacterial extract and antibodies which are directed against *H. pylori* and which are present in the sample.

Claim 38, line 8, change "such as obtained" to --obtainable--.

REMARKS

I. Status of Claims

Claims 31-42 are pending. Claims 31-36 are withdrawn as directed to non-elected subject matter. This Amendment amends claims 37 and 38. No new matter is added.

II. Priority

The Office Action indicates that a claim for priority cannot be based on the application filed in France on "4-7-95" since the United States application was filed more than twelve months thereafter. Applicants respectfully submit that the Claim for priority filed in the parent application on August 7, 1996 properly indicates that the French Application No. 9,508,068 was filed on July 4, 1995 and not April 7, 1995, as indicated on the Rule 53(b) Application Transmittal. In support of this position, Applicants refer the Examiner to the Declaration/Power of Attorney which properly claims priority of the French Application 95 08068 filed on "04/07/1995." It is common practice in many foreign countries, such as France and Japan, to recite the day before

the month, which is opposite of the practice in the United States. Based on this practice, Applicants respectfully submit that the above-identified application can claim priority based on the French application. Reconsideration and acknowledgment of the claim for priority are respectfully requested.

III. Information Disclosure Statement

An Information Disclosure Statement with Form PTO-1449 was filed in the above-identified patent application. The Examiner initialed some of the references indicated on the PTO-1449, but not others because some of the references were missing from the Patent Office file. Copies of the references that were not acknowledged are enclosed as well as relevancy statements for the non-English language references.

The Examiner is requested to initial and return to the undersigned a copy of the Form PTO-1449 indicating that all of the references have been considered.

IV. Drawings

The Office Action indicates that Figures 1-13 are absent from the instant application. Enclosed is a copy of the Rule 53(b) transmittal indicating that a complete copy of the prior application "including oath or Declaration and drawings" was filed on January 29, 1998. Additionally, enclosed is the stamped post card receipt indicating same. For the convenience of the Examiner, copies of Figures 1-13 are attached hereto.

V. Rejections Under § 112, second paragraph

A. Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, because it is allegedly unclear which nucleotide sequences are hybridizing. Applicants respectfully traverse the rejection.

One of ordinary skill in the art would readily understand that the "nucleotide sequence of a *flbA* gene regulating biosynthesis of a flagellar protein of *H. pylori*" hybridizes "with a probe which corresponds to...". Additionally, one of ordinary skill in the art would readily understand that the probe "has been amplified using two oligonucleotide sequences...". Thus, claim 37 particularly points out and distinctly claims the subject matter of the invention. Reconsideration and withdrawal of the rejection are respectfully requested.

B. Claim 38 is rejected under 35 U.S.C. § 112, second paragraph, because it is unclear what is obtained by the steps. Claim 38 has been amended to overcome the rejection. Reconsideration and withdrawal of the rejection are respectfully requested.

VI. Rejection Under § 102(b)

Claims 37-41 are rejected under 35 U.S.C. § 102(b) over Haas et al., Mol. Microbiol, 1993, 8(4), pp. 753-60. Applicants respectfully traverse the rejection.

Haas et al. teach a transposon shuttle mutagenesis approach for *H. pylori* based on transformation of naturally competent strains with a cloned, transposon-inactivated

gene. See page 757, Discussion. In particular, plasmids carrying the *cat*-inactivated *flaA* gene were efficiently taken up by competent *H. pylori* cells and subsequently recombined into the chromosome via a double crossover event, resulting in an inactivated chromosomal gene. This is a general method of generating defined mutants in *H. pylori* and not a method of detecting an infection in a sample from a patient. In particular, Haas et al. does not teach a method for the *in vitro* detection of an infection due to *H. pylori* in a sample of biological fluid from a patient comprising a) bringing the sample into contact with a bacterial strain...and b) detecting an immunological reaction between the bacterial strain...and antibodies which are directed against *H. pylori* and which are present in the sample, as recited in the claims.

Thus, Haas et al. does not anticipate the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

VII. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that the above-identified application is in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

If there are any other fees due in connection with the filing of this Amendment, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an

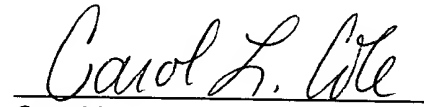
Attorney Docket No. 02356.0073-01

extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By:



Carol L. Cole

Reg. No. 43,555

Dated: February 25, 2000

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, D. C. 20005
202-408-4000